

**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: Q88273

Pyare L. SETH

Appln. No.: 10/540,422

Group Art Unit: 1612

Confirmation No.: 4203

Examiner: Lezah ROBERTS

Filed: April 4, 2006

For: PHARMACEUTICAL LIQUID COMPOSITION CONTAINING PYRIDONE  
DERIVATIVE

**STATEMENT OF SUBSTANCE OF INTERVIEW**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Please review and enter the following remarks summarizing the telephonic interviews conducted on May 7, 11, and 28 and July 1, 2009:

**REMARKS**

An Examiner's Interview Summary Record (PTO-413) was attached with the Notice of Allowance dated June 11, 2009.

The interview was initiated by the Examiner. Therefore, no further recordation by the Applicant is believed to be required.

This STATEMENT OF SUBSTANCE OF INTERVIEW is being submitted in response to the Interview Summary attached to the Notice of Allowance mailed June 11, 2009, which requires Applicants to file a Statement of Substance of Interview within one month or thirty days from the Interview date, whichever is longer. Therefore, **Applicants should not be charged**

**with a reduction of PTA since this Statement of Substance of Interview was necessitated by  
the Interview Summary attached to the Notice of Allowance mailed June 11, 2009.**

During the interview, the following was discussed:

1. Brief description of exhibits or demonstration: None.
2. Identification of claims discussed: pending.
3. Identification of art discussed: None
4. Identification of principal proposed amendments: See attached draft Third

Examiner's Proposed Amendment prepared by the undersigned for the Applicants' review.

5. Brief Identification of principal arguments: None.
6. Indication of other pertinent matters discussed: Upon review of the Examiner's

Amendment attached to the Notice of Allowance mailed June 11, 2009, Applicants' representative noted that the word "about" in the phrase in claim 1, "in a concentration of 10% to about 25%" was not supposed to be deleted per the telephonic conversations between the undersigned and the Examiner.

7. Results of Interview: Examiner indicated she would check with her supervisor regarding the unauthorized deletion of the word "about" and Applicants' representative requested a corrected or supplemental Examiner's Amendment.

It is respectfully submitted that the instant STATEMENT OF SUBSTANCE OF INTERVIEW complies with the requirements of 37 C.F.R. §§1.2 and 1.133 and MPEP §713.04.

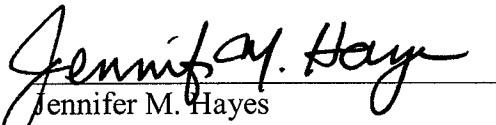
**It is believed that no petition or fee is required.** However, if the USPTO deems otherwise, Applicant hereby petitions for any extension of time which may be required to

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maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,

  
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Date: July 1, 2009

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**THIRD EXAMINER'S PROPOSED AMENDMENT**

**LISTING OF CLAIMS:**

**1. (currently amended):** A pharmaceutical liquid composition comprising 5-methyl-1-phenyl-2-(1H)-pyridone (**Pirfenidone**) or a pharmaceutically acceptable salt thereof in a concentration of 10% to about 25% by weight, wherein the solvent is and dissolved in a diethylene glycol monoethyl ether solvent, said composition comprising in a concentration of 70-80% by weight of said solvent.

**2.-3. (canceled).**

**4. (previously presented):** A pharmaceutical liquid composition according to Claim 1, wherein the diethylene glycol monoethyl ether has a purity of 99% or higher.

**5. (currently amended):** A pharmaceutical liquid composition according to Claim 1, further comprising a concentrating agent polyvinylpyrrolidone, hydroxypropylcellulose or hydroxypropyl methylcellulose.

**6. (previously presented):** A pharmaceutical liquid composition according to Claim 1, further containing an antioxidant.

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**7. (original):** A pharmaceutical liquid composition according to Claim 6, wherein the antioxidant is an  $\alpha$ -tocopherol.

**8. (previously presented):** A pharmaceutical liquid composition according to Claim 1, in the form of an oral, percutaneous, nasal or vaginal preparation or in the form of a spray, patch, inhalant, injection or intravenous drip.

**9. (currently amended):** A pharmaceutical liquid composition according to Claim 1, having the following components:

<u>Ingredients</u>	<u>% by weight</u>
<u>5-methyl-1-phenyl-2-(1H)-pyridone</u> Pirfenidone	10-25
Diethylene glycol	
monoethyl ether	70-80
Ethanol (95%)	0-10
Polyvinyl pyrrolidone or	
hydroxypropyl cellulose	0-3
Sodium metabisulfite	0.02-2

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Methyl or propyl	
paraben	0-0.5
<u>Purified water</u>	<u>0-25.</u>

**10. (currently amended):** A pharmaceutical liquid composition according to Claim 1, having the following components:

<u>Ingredients</u>	<u>% by weight</u>
<u>5-methyl-1-phenyl-2-(1H)-pyridone</u> <b>Pirfenidone</b>	10-25
Diethylene glycol	
monoethyl ether	75-80
<u>Purified water</u>	<u>0-10.</u>

**11. (currently amended):** A pharmaceutical liquid composition according to Claim 181, having the following components:

<u>Ingredients</u>	<u>% by weight</u>
<u>5-methyl-1-phenyl-2-(1H)-pyridone</u> <b>Pirfenidone</b>	10-25
Diethylene glycol	

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monoethyl ether	75-80
$\alpha$ -Tocopherol	0.1-0.5
Hydroxypropyl cellulose	0-3
<u>Purified water</u>	<u>0-10</u> .

**12. (currently amended):** The pharmaceutical composition according to claim 1,  
wherein the composition ~~has good stability~~is stable.

**13. (previously presented):** The pharmaceutical composition according to claim 1,  
wherein the composition does not cause skin irritation.